

**510(k) Summary**

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**Date:**

May 10, 2013

**Submitter Information**

CooperVision, Inc.  
6150 Stoneridge Mall Road  
Suite 370  
Pleasanton, CA 94588  
USA  
(800) 972-6724

**AUG 30 2013****Contact**

Annette Nelson  
Dept. of Regulatory Affairs  
[anelson@coopervision.com](mailto:anelson@coopervision.com)  
(925) 621-2453

**Device Identification**

Common Name: Soft Contact Lens

Trade Name: SUS (stenfilcon A) Soft Contact Lens

Class. Name: Soft (hydrophilic) Contact Lens – Daily Wear; Disposable

Classification: Class II [21 CFR 886.5925 (b) (1)]

Product Code: LPL, MVN

**Predicate Device(s)****Material**

CooperVision AVAIRA (enfilcon A)  
K071736  
(Silicone Hydrogel)

**Indication, Wear Schedule**

CooperVision CLEARSIGHT 1 DAY (ocufilcon B)  
K020389 (Daily wear, single use)

## **510(k) Summary, continued**

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### **Description of Device**

- The SUS (stenfilcon A) Contact Lens Visibility Tinted with UV Blocker is available as an aspherical lens, toric lens, multifocal lens, and multifocal toric lens.
- The lenses are made of a silicone hydrogel material which is not surface treated and is characterized by high oxygen permeability (Dk).
- The SUS (stenfilcon A) Contact Lens is tinted blue using Reactive Blue #246 to make the lens more visible for handling.
- A Norbloc UV Blocker is used to reduce the amount of ultraviolet light transmitted into the eye.
- The SUS (stenfilcon A) lens is supplied sterile, packaged in a buffered saline solution.
- The composition of the lens is 46% stenfilcon A and 54% water by weight when hydrated and stored in buffered saline solution.

## 510(k) Summary, continued

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### Indications for Use

| Lens Design      | Indication  |
|------------------|---|
| Aspherical       | SUS (stenfilcon A) ASPHERE Soft Contact Lenses are indicated for the correction of ametropia (myopia and hyperopia) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00D to +20.00D diopters. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity.   |
| Toric            | SUS (stenfilcon A) TORIC Soft Contact Lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.  |
| Multifocal       | SUS (stenfilcon A) MULTIFOCAL Soft Contact lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of -2.00 diopters or less that does not interfere with visual acuity. |
| Multifocal Toric | SUS (stenfilcon A) MULTIFOCAL TORIC Soft Contact lenses are indicated for the optical correction of distance and near vision in presbyopic phakic or aphakic persons with non-diseased eyes who may have -10.00 diopters of astigmatism or less.  |

## 510(k) Summary, continued

### Technological Characteristics:

The technological characteristics of the SUS (stenfilcon A) Contact Lenses are compared to the characteristics of the predicate device, CooperVision AVAIRA (enfilcon A) Contact Lens, in the following tables.

| Material Comparison  |                                     |                                    |
|----------------------|-------------------------------------|------------------------------------|
|                      | Predicate Device                    | Subject Device                     |
| Product Name         | CooperVision<br>AVAIRA (enfilcon A) | CooperVision<br>SUS (stenfilcon A) |
| Material USAN Name   | Enfilcon A                          | Stenfilcon A                       |
| 510(k) Number        | K071736                             | TBD – Current Submission           |
| FDA Category (Group) | Silicone Hydrogel                   | Silicone Hydrogel                  |
| Manufacturing Method | Molded                              | Molded                             |
| Sterilization        | Moist Heat                          | Moist Heat                         |
| Packaging            | Blister                             | Blister                            |
| Visibility Tint      | Phthalocyanine Blue                 | Reactive Blue #246                 |

| Parameter Comparison      |  |         |  |         |
|---------------------------|--|---------|--|---------|
|                           | Predicate Device<br>CooperVision<br>Avaira (enfilcon A)<br>K071736 |         | Subject Device<br>CooperVision<br>SUS (stenfilcon A)<br>TBD – Current Submission |         |
|                           | Measured   | Labeled | Measured   | Labeled |
| Water Content, %          | 45%  | 46%     | 54.3%  | 54%     |
| Refractive Index @ 20°C   | 1.402  | 1.40    | 1.4011   | 1.40    |
| *Oxygen Permeability (Dk) | 99.6   | 100     | 79.2   | 80      |
| Base Curve, mm            | 8.45   | 8.5     | 8.33   | 8.4     |
| Diameter, mm              | 14.26  | 14.2    | 14.12  | 14.2    |

\*Dk units: (cm/sec)x(ml O<sub>2</sub>)/(ml x mm Hg)

## 510(k) Summary, continued

### Technological Characteristics:

The technological characteristics of the SUS (stenfilcon A) Contact Lenses are compared to the characteristics of the predicate device, CooperVision CLEAR SIGHT 1 DAY (ocufilcon B) Contact Lens, in the following tables.

| Material Comparison  |  |                                    |
|----------------------|--|------------------------------------|
|                      | Predicate Device                                   | Subject Device                     |
| Product Name         | CooperVision<br>CLEAR SIGHT 1 DAY<br>(ocufilcon B) | CooperVision<br>SUS (stenfilcon A) |
| Material USAN Name   | Ocufilcon B  | Stenfilcon A                       |
| 510(k) Number        | K020389  | TBD – Current Submission           |
| FDA Category (Group) | Group IV   | Silicone Hydrogel                  |
| Manufacturing Method | Molded   | Molded                             |
| Sterilization        | Moist Heat   | Moist Heat                         |
| Packaging            | Blister  | Blister                            |
| Visibility Tint      | Vat Blue 6   | Reactive Blue #246                 |

| Parameter Comparison      |   |         |  |         |
|---------------------------|---|---------|--|---------|
|                           | Predicate Device<br>CooperVision<br>CLEAR SIGHT 1 DAY<br>(ocufilcon B)<br>K020389 |         | Subject Device<br>CooperVision<br>SUS (stenfilcon A)<br>TBD – Current Submission |         |
|                           | Measured  | Labeled | Measured   | Labeled |
| Water Content, %          | 51.04   | 52%     | 54.3%  | 54%     |
| Refractive Index @ 20°C   | 1.415   | 1.41    | 1.4011   | 1.40    |
| *Oxygen Permeability (Dk) | 16.17   | 16.8    | 79.2   | 80      |
| Base Curve, mm            | 8.85  | 8.7     | 8.33   | 8.4     |
| Diameter, mm              | 14.12   | 14.2    | 14.12  | 14.2    |

\*Dk units: (cm/sec)x(ml O<sub>2</sub>)/(ml x mm Hg)

## **510(k) Summary, continued**

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### **Non-clinical Testing**

A series of in-vitro and in-vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the contact lens. All tests were conducted in accordance with the GLP regulation (21 CFR Part 56) or according to valid scientific protocols.

The results of the non-clinical testing/evaluation demonstrate that:

- The lens material and/or extracts are non-toxic, non-irritating and non-sensitizing under the experimental conditions; and
- The lens physical and material properties are consistent with currently marketed lenses. The following tests were performed to show substantial equivalence:
  - Extractables – Residuals by Soxhlet extraction
  - Modulus, Elongation and Tensile Strength Testing
  - Oxygen Permeability and Transmissibility
  - Water Content
  - Light Transmittance
  - Refractive Index
  - Contact Angle
  - Lens Parameters
  - Shelf Life

### **Clinical Testing**

A three-month clinical study was completed to evaluate the safety and efficacy of the SUS (stenfilcon A) Contact Lens for daily wear, single use only.

The study evaluated ninety (90) male and female subjects who were randomized and dispensed lenses in a 2:1 ratio with 60 subjects dispensed into the Test lenses and 30 subjects dispensed into the Control lenses. The primary outcome measures were biomicroscopy and adverse event rates along with lens visual acuity comparisons between the Test and the Control contact lenses. Secondary outcome measures included average lens wearing times and subjective lens comfort assessed by frequency or symptoms.

The Test contact lens was found to be substantially equivalent to the Control contact lens for safety and efficacy.

## **510(k) Summary, continued**

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### **Conclusion Drawn from Studies**

#### **Validity of Scientific Data:**

A contract laboratory under Good Laboratory Practice Regulations conducted toxicology studies. Microbiology, chemistry, shelf-life stability, and leachability studies were conducted by CooperVision laboratories and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.

#### **Substantial Equivalence:**

Information presented in this Premarket Notification establishes that the SUS (stenfilcon A) Contact Lens is as safe and effective as the predicate device when used in accordance with the labeled directions for use and the requested indication.

#### **Risk and Benefits:**

The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear single use basis. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

August 30, 2013

CooperVision, Inc.  
% Ms. Annette Nelson  
Senior Regulatory Affairs Specialist  
6150 Stoneridge Mall Road, Suite 370  
Pleasanton, CA 94588

Re: K131378

Trade/Device Name: SUS (stenfilcon A) Soft (hydrophilic) Contact Lens  
Regulation Number: 21 CFR 886.5925  
Regulation Name: Soft (hydrophilic) contact lens  
Regulatory Class: II  
Product Code: LPL, MVN  
Dated: July 15, 2013  
Received: July 16, 2013

Dear Ms. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.



You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Kesia Y. Alexander -S**

for Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic and  
Ear, Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K131378

Device Name: SUS (stenfilcon A) Soft (hydrophilic) Contact Lenses for Single Use  
Daily Wear

### Indications for Use:

#### Aspherical

SUS (stenfilcon A) ASPHERE Soft Contact Lenses are indicated for the correction of ametropia (myopia and hyperopia in aphakic and non-aphakic persons with non-diseased eye in powers from -20.00 D to +20.00 D. The lenses may be worn by persons who exhibit astigmatism of -2.00 D or less that does not interfere with visual acuity.

#### Toric

SUS (stenfilcon A) TORIC Soft Contact Lenses are indicated for the correction of ametropia (myopia or hyperopia with astigmatism) in aphakic and non-aphakic persons with non-diseased eyes in powers from -20.00 to +20.00 diopters and astigmatic corrections from -0.25 to -10.00 diopters.

#### Multifocal

SUS (stenfilcon A) MULTIFOCAL Soft Contact Lenses are indicated for the correction of refractive ametropia (myopia and hyperopia) and emmetropia with presbyopia in aphakic and non-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of -2.00 D or less that does not interfere with visual acuity.

#### Multifocal toric

SUS (stenfilcon A) MULTIFOCAL TORIC Soft Contact Lenses are indicated for the optical correction of distance and near vision in presbyopia phakic or aphakic persons with non-diseased eyes who may have 10.00 D of stigmatism or less.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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